REMARKS

In the Official Action mailed 02 December 2008, the Examiner reviewed claims 6, 7, 10-16, 19, 20, 22-25, 27 and 28. The Examiner has objected to claim 15 for informalities; has rejected claim 6 under 35 U.S.C. §102(b); has rejected claims 7 and 28 under 35 U.S.C. §103(a); and has rejected claims 10-16, 19, 20, 22-25 and 27 under 35 U.S.C. §103(a).

Applicant has canceled claims 22-24, added claim 57-59, and amended claims 6, 10, 14, 15, 19 and 25. After entry of this amendment, claims 6, 7, 10-16, 19, 20, 25, 27, 28 and 57-59. will remain pending in this case.

Objection to Claims 15

The Examiner has objected to claim 15 for informalities. Claim 15 is amended to correct the error.

Rejection of Claim 6 under 35 U.S.C. §102(b)

The Examiner has rejected claim 6 under 35 U.S.C. §102(b) as being anticipated by Kavteladze (WO 95/27448).

Rejection of Claims 7 and 28 under 35 U.S.C. §103(a)

The Examiner has rejected claims 7 and 28 under 35 U.S.C. §103(a) as being unpatentable over Kavteladze (WO 95/27448).

Rejection of Claims 10-16, 19, 20, 22-25 and 27 under 35 U.S.C. §103(a)

The Examiner has rejected claims 10-16, 19, 20, 22-25 and 27 under 35 U.S.C. §103(a) as being unpatentable over Kavteladze (WO 95/27448) in view of Marks (US 5,108,420).

The Cited Art

The patent to **Kavteladze** shows several examples of one or two conical filters formed as bodies of revolution (10, 11; 30; 18; 40, 41), each body of revolution having an apex and a base. An elastic occlusion membrane (16; 32; 19; 42) can be used with the bodies of revolution. In the embodiment shown in the figures with 2 bodies of revolution (figures 3-5, 6, 9), the membrane is a disc shaped member secured at the joined apices; the membrane extends perpendicular to the axis and

is space apart from the bodies of revolution. The embodiment of figure 7 shows membrane 19 joined at the apex of a single body of revolution 18; membrane 19 is supported by an umbrella-like structure 20 to form a shallow conical member spaced apart from body of revolution 18. The device of Kavteladze is introduced to the target site within an introduction catheter and is ejected from the introduction catheter using a pushing member sliding within the catheter. (Column 4, lines 41-49 and 53-56.) The invention of Kavteladze is designed for permanent or semipermanent placement in the vascular system to act as a filter or as an occlusion device. It can also be used to seal a hole in the atrial septum (figure 8) or to seal an opening in the ductus arteriosis to prevent recirculation of arterial blood through the lungs (figure 7).

The patent to **Marks** discloses an aperture closure device 27 used to occlude holes in a body wall or membrane, such as a septal defect in a heart. Device 27 includes two membranes 21 mounted on a shape memory wire rims 23. The wire rims are preferably thermal shape change material and assume outwardly flaring shapes when heated to body temperature. Device 27 is placed in a pot 11 of a deployment catheter 19 for positioning through and to the distal side of an aperture 68 in a wall 68a. Once in position, device engaging catheter 13 is pushed so the distal most device 27a exits pod 11 and expands. Release wire 15, which has a knuckle 15a at its distal end, engages eye 25 connected to the wire ribs 23, is pulled to pull device 27a against the surface of wall 68. Deployment catheter 19 is then removed from the proximal device 27b to permit it to assume its expanded shaped so that device 27 seals aperture 68 as shown in figures 2 and 5.

The Cited Art Distinguished

Claim 6 is distinguishable from Kavteladze for several reasons.

First: Claim 6 recites in part "inserting a catheter into a body passageway" and "radially expanding the blood flow blocking element into a radially expanded, passageway sealing state extending to the wall of the body passageway ...." That is, the blood flow blocking element is expanded into the same body passageway at the catheter had been inserted into. In contrast, with regard to **figures 7 and 8**, the patent to Kavteladze discloses procedures dealing with sealing holes in the atrial septum and the ductus arteriosis. With these procedures the blood flow blocking element does not extend to the wall of the body passageway through which it was inserted, but rather on each side of a layer of tissue with a hole in it.

Second: Claim 6 has been amended to recite "a balloon-less blood flow blocking element comprising a blood flow blocking surface with structural members which define openings

therebetween" and "the generally funnel surface being the blood flow blocking surface...." In contrast, Kavteladze discloses in **figures 1, 3-5** that what could be considered a funnel surface is not a blood flow blocking surface. Rather, the occlusion element of Kavteladze is provided by a separate, disk-shaped elastic membrane 16, 32, 42. It would not have been obvious to cover the bodies of revolution of Kavteladze with an elastic membrane because, applicant submits, doing so would likely change the operational characteristics of the body of revolution.

Third: Claim 6 has also been amended to emphasize that the blood flow blocking element is affixed to the catheter. In contrast, Kavteladze is directed to a completely different type of device that is the permanently or semi-permanently placed into the patient. The device of Kavteladze is not affixed to the introducer catheter but rather it slideably housed within the introducer catheter and then ejected by some type of pushing member.

Accordingly, claim 6 is allowable over the cited art. Independent claims **10, 15, 19 and 25** have been amended in a similar manner and are allowable for the same basic reasons.

The **dependent claims** are directed to specific novel subfeatures of the invention and are allowable for that reason as well as by depending from novel parent claims. For example, new **claim 57** recites "maintaining the catheter with the blood flow blocking element affixed thereto within the body passageway; and following the catheter maintaining step: radially contracting the blood flow blocking element; and removing the catheter and the blood flow blocking element therewith from the body passageway." In contrast, the Kavteladze and Marks patents do not leave their respective devices affixed to the placement catheter within the passageway during a procedure because the devices of Kavteladze and Marks appear to be intended for permanent or semipermanent placement so that leaving their devices affixed to a placement catheter would be contrary to their teachings. New claims 58 and 59 are similar.

CONCLUSION

It is respectfully submitted that this application is now in condition for allowance, and such action is requested. If the Examiner believes a telephone conference would aid the prosecution of this case in any way, please call the undersigned at (650) 712-0340.

The Commissioner is hereby authorized to charge any fee determined to be due in connection with this communication, or credit any overpayment, to our Deposit Account No. 50-0869 (GTEC 1001-5).

Respectfully submitted,

Dated: 02 March 2009

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